

**October 15, 2007 – News Release**

## **Affectis Pharmaceuticals AG Starts Phase II Clinical Trial with Cimicoxib for Depression**

Munich, Germany – Affectis Pharmaceuticals AG, a biopharmaceutical company developing novel drugs for depression and schizophrenia, today announced the start of a clinical Phase II trial to study the efficacy and safety of Cimicoxib as a treatment for depression. The first patient has been enrolled at the Clinic of Psychiatry and Psychotherapy at the Ludwig-Maximilians-University in Munich. This double-blind, randomised, placebo controlled study will include a total of 134 patients and is being conducted at multiple centres in Germany. The primary endpoint of the study is a clinically relevant improvement in the Hamilton Depression Rating Scale.

Cimicoxib is a selective COX-2 inhibitor being developed by Affectis as a treatment for depression and schizophrenia. Affectis in-licensed Cimicoxib from Palau Pharma in early 2007. Cimicoxib is characterised by a good safety profile as demonstrated in 5 clinical studies in which a total of 261 subjects received the drug. The compound also showed efficacy at 3 doses in a Phase II study in post-operative pain conducted by Palau.

"We are starting our first Phase II trial with Cimicoxib a relatively short time after in-licensing the compound," said Herbert Stadler, CEO of Affectis. "By preparing this study and receiving the necessary regulatory approvals in a timely manner, our team has once again demonstrated its ability to execute. If approved, Cimicoxib would be the first drug in decades to treat depression by a new mechanism of action. Clearly, this would represent a significant advance in the treatment of this serious disorder. With the start of the trial, we are pleased to have taken a meaningful step towards that goal."

COX-2 inhibitors have been shown to successfully treat patients suffering from depression and schizophrenia in double-blinded, placebo-controlled academic studies published in peer reviewed journals. In depression, patients receiving a COX-2 inhibitor in addition to standard treatment for 6 weeks showed significantly greater improvement in scores of the Hamilton Depression Rating Scale than patients receiving standard treatment plus placebo. Affectis Pharmaceuticals owns granted patents for the use of COX-2 inhibitors as treatments for depression and schizophrenia.

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## **Notes to Editors**

### **About Affectis Pharmaceuticals AG**

Affectis is a biopharmaceutical company implementing novel concepts for the treatment of mental disorders, especially depression and schizophrenia. The Company has unique capabilities to discover and develop drugs based on pioneering findings in the field of mental disorders. These drugs address the increasing need for more comprehensive and faster-acting antidepressants with fewer side effects. Affectis started operations in November 2003 as a spin-off from the renowned Max-Planck-Institute of Psychiatry, a world leader in the field of psychiatric research. A strong team of executives and scientists with long-term industry experience contribute to Affectis' progress. The Company raised its third round of venture financing in October 2006, led by Aescap Venture. Affectis is based in Munich, Germany.

For more information, please visit [www.affectis.com](http://www.affectis.com)

### **About Cimicoxib**

Cimicoxib is a novel highly selective COX-2 inhibitor developed by Affectis as a treatment against depression and schizophrenia. Patients with major depression often show signs of inflammatory processes, especially elevated levels of prostaglandin E2 (PGE2), an important mediator of inflammation, and of pro-inflammatory cytokines. Coxibs are drugs inhibiting cyclooxygenase-2 (COX-2), thereby blocking the production of PGE2 and pro-inflammatory cytokines.

At present, Coxibs are approved for other inflammation-related diseases such as osteoarthritis, rheumatoid arthritis and ankylosing spondylitis as well as for primary dysmenorrhoea, and for the treatment of acute pain in adults.

### **About Hamilton Depression Rating Scale**

The Hamilton Depression Rating Scale is an established standard measure of depression and based on a multiple-choice questionnaire. It is used to assess the severity of a depression and clinical changes in patients during treatment.